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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/046,840	03/24/1998	DAKAI LIU	ENZ-56(DIV3)	2602
28171	7590	12/21/2007		
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			EXAMINER GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			12/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/046,840

Applicant(s)

LIU ET AL.

Examiner

David Guzo

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 85-103 and 111-113 is/are allowed.
- 6) ☒ Claim(s) 104-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/14/03, 3/17/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/3/07 has been entered.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 104-110 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Wong-Staal et al.

This rejection (as it pertains to claims 104-107) is repeated for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include claims 108-110.

With regard to claims 108-110, the cell lines disclosed by Wong-Staal et al. comprise non-retroviral sequences which include AAV ITRs which can function as a promoter and comprise integration sequences as well as a marker gene.

Applicants argue that since the amended claims now recite cells comprising packaging components for producing a non-retroviral vector, the claims are distinguished from Wong-Staal et al. Applicants indicate that Wong-Staal et al. teach a first vector that is a non-retroviral vector (AAV) that generates a second vector which is a retroviral vector. The instantly claimed first vector (retroviral vector) produces a second vector (non-retroviral vector) and applicants assert that this teaching is lacking in Wong-Staal's disclosure.

Applicant's arguments filed 9/14/05 have been fully considered but they are not persuasive. The instant claims (claim 104 and claims dependent upon it) recite a cell line comprising several elements. The cell lines of Wong-Staal et al. recite the same elements, i.e. 1) retroviral sequences (HIV sequences), 2) non-retroviral vector sequences (i.e. AAV sequences), 3) nucleic acid sequences encoding an exogenous gene such as a marker (i.e. CAT), 4) packaging components for producing a non-retroviral vector (i.e. AAV ITR, cap gene, etc. sequences). Wong-Staal et al. therefore teaches the claimed invention. The instant claims do not recite the limitations that applicants argue, i.e. the characteristics of a "first" and "second" vector.

Claims 104-105 and 108-110 are rejected under 35 U.S.C. 102(e) as being anticipated by Curiel et al.

This rejection (as it pertains to claims 104-105) is repeated for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include claims 108-110.

With regard to Claims 108-110, the cell lines disclosed by Curiel et al. comprise non-retroviral sequences which include adenoviral promoters (i.e. E2 or E4 gene promoters, etc.) and terminators for said genes as well as an exogenous marker gene (*LacZ* cDNA).

Applicants traverse this rejection by asserting that Curiel discloses a first vector which is a non-retroviral vector, namely, adenovirus, that generates a second vector which is a retroviral vector. Thus, a material element in the form of Applicants' second viral vector which is a non-retroviral vector, is altogether lacking in Curiel's patent.

Applicants' arguments have been considered but are not persuasive. The instant claims (claim 104 and claims dependent upon it) recite a cell line comprising several elements. The cell lines of Curiel et al. recite the same elements, i.e. 1) retroviral sequences (LTRs, gag/pol/env), 2) non-retroviral vector sequences (i.e. adenoviral sequences such as ITRs, E2, E4 genes, etc.), 3) nucleic acid sequences encoding a exogenous gene such as a marker (i.e. *LacZ* cDNA), 4) packaging components for producing a non-retroviral vector (i.e. adenoviral ITR sequences, E2, E4, L1-L5 genes, etc.). Curiel et al. therefore teaches the claimed invention. The instant claims do not recite the limitations that applicants argue, i.e. the characteristics of a "first" and "second" vector. Also, the adenoviral packaging components can produce a non-

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retroviral vector in the cells disclosed by Curiel et al. if said cells are infected with an adenoviral helper virus.

The substitute drawings submitted 9/14/05 are acceptable and have been entered.

Any rejections not repeated in this Office Action are withdrawn.

Claims 85-103 and 111-113 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVID GUZO
PRIMARY EXAMINER

David Guzo
December 16, 2007